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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,588	01/21/2000	Mark C. Shults	DEXCOM-04114	6019

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,588

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 28-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 28-71 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- ☐ Interview Summary (PTO-413) Paper No(s). ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 28-71 are rejected in that it is unclear exactly what the scope of "continuous glucose sensing" is as defined by applicant. Continuous glucose sensing is generally meant to refer to a measurement type that is not discrete, e.g. it continuously makes measurements. Applicant purports to provide a different definition on page 9 on the specification. It is unclear to the examiner why this is different than a conventional sensing device.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is rejected in that it recites that the glucose determining apparatus comprises a bioprotective layer, and that the bioprotective layer is more distal with respect to the housing than the glucose determining apparatus. It is unclear how the bioprotective layer can be distal with respect to the glucose determining

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apparatus when it is part of the glucose determining apparatus. Claims 29-42 are rejected as being dependent on a rejected base claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 69 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Picha figure 8.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28, 37-39, 42, 43-46, 48-56, and 60-62 are rejected under 35 U.S.C. 103(a) as being obvious over Schulman et al in view of Ward et al and Picha. Schulman et al has a housing 52, including an electronic circuit and two electrodes connected to the circuit (see figure 4a), and a sensor operable connected to the electrodes, a membrane 100 impregnated with an oxidase, and a bioprotective layer 96, substantially impermeable to microphages. It does not have the device for determining glucose concentration or the angiogenic layer. However, Ward et al is selected from a

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myriad references that teach wirelessly transmitting the signal out of the body is an alternative method to hard wiring the sensor out of the body. As such, Ward et al has a device 126 that determines changes in glucose levels. Hence, it would have been obvious to modify Schulman et al to include a device for determining glucose levels internally, to simplify the overall construction of the device. In addition, Picha teaches that implantable sensor will function longer and more accurately if an exterior layer that allows tissue ingrowth is included. Hence, it would have been obvious to modify Schulman et al to include such an exterior layer to improve its accuracy. This allows for "continuous glucose monitoring, as defined by applicant. Claim 37 is rejected in that the examiner takes official notice that the recited materials are well known to be used for semi-permeable membranes. Claim 38 is rejected in that the exact pore size would have been obvious to one skilled in the art. Claim 39 is rejected in that Picha uses open celled foam for the angiogenic layer 14. The examiner takes official notice that the claimed materials are well known to be used in open celled foams. Claim 42 is rejected in that it is well known to secure a circuit with waxes and resins. Claims 53-56 and 60 are rejected for the reasons given above.

Claims 63-65, 67, and 71 are rejected under 35 U.S.C. 103(a) as being obvious over Picha in view of Ward et al. Picha shows all of the features of these claims except it that it is not wholly implantable. However, Ward et al is selected from a myriad references that teach wirelessly transmitting the signal out of the body is an alternative method to hard wiring the sensor out of the body. Hence, it would have been obvious to

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modify Picha to use the transmitter of Ward et al, to simplify overall construction of the implantable device.

Claims 29-36, 40-41, 47, 57-59, 66, 68, and 70 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg, can be reached on (703) 308-3130. The fax phone number for this Group is (703) 308-0758.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [max.hindenburg@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

RLN
6/4/03

Robert L. Nasser Jr.
ROBERT L. NASSER
PATENT EXAMINER